"This conference was very useful to hear first-hand information on new initiatives... and network with colleagues"
M. Crnogorac, *Genentech*

The Parenteral Drug Association presents the...

2011 PDA/FDA Joint Regulatory Conference & TRI Courses

Quality and Compliance in Today's Regulatory Enforcement Environment

September 19-23, 2011

Renaissance Hotel
Washington, D.C.

Register Before **July 9th** - The First Registration Savings Deadline!

CONFERENCE September 19-21 **EXHIBITION** September 19-21 **COURSES** September 22-23

www.pda.org/pdafda2011

This preliminary agenda is current as of May 20, 2011.

Program Planning Committee

Amy Giertych, Co-Chair
Baxter Healthcare Corporation

Susan Schniepp, Co-Chair
OSO BioPharmacueticals Manufacturing

Douglas Campbell
CDER, FDA

David Cumming
OPS, FDA

Robert Dana
PDA TRI

J. David Doleski
DMPQ, CBER, FDA

John Finkbohner, PhD
MedImmune, Inc.

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CDRH, FDA

Kathleen Greene
Novartis Pharmaceuticals

Maria Guazzaroni-Jacobs
Pfizer, Inc.

Adrienne Hornatko-Munoz
CBER, FDA

Mai Huynh
CVM, FDA

Louise Johnson
Takeda Pharmaceuticals

Elizabeth Leininger, PhD
E Leininger Consulting

Jim Lyda
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Vince Mathews
Eli Lilly & Company

Steven Mendivil
Amgen, Inc.

Wanda Neal
PDA

Kenneth Nolan
OER/OC, FDA

Laurie Norwood
DMPQ, CBER, FDA

Stephan Roenninger, PhD
F. Hoffman-LaRoche, Ltd.

Timothy Tomkovich
Abbott Global Pharmaceutical Operations

Ruby Tiwari, Pharm.D.
DMPQ, FDA

Andrea Viera
PDA

Lonnie Warren-Henderson
CBER, FDA

Barbara Zinck
Zinck Consulting

A Message from the Program Co-Chairs

Dear Colleague,

The *2011 PDA/FDA Joint Regulatory Conference & TRI Courses* is just around the corner. This year's conference titled "*Quality and Compliance in Today's Regulatory Enforcement Environment*" will take place September 19-23 in Washington DC and promises to be one of the best conferences to date. The theme was inspired by recent regulatory actions (483's, Warning Letters, etc.) being issued to the global pharmaceutical industry.

The backbone of the conference is based on the 3 learning tracks for conference attendees to choose from: Foundations, Quality/Compliance, and Innovation/Regulatory Science. The Foundations track is focused on getting back to regulatory and quality basics so companies are prepared to address increased regulatory scrutiny. Individual sessions discussing Foreign Inspections, First Cycle Review, Recognized Standards, are all planned in addition to a breakfast session titled "Ask the Regulator: CDER Compliance. The Quality and Compliance track was planned to discuss some of the new global compliance initiatives and includes sessions on New Regulations, Good Inspection Practices, and an International Update from the FDA perspective. The Innovation/Regulatory Science track will focus ICH Q11, Drug Safety, and a discussion on GMP requirements by Phase Development.

Attendees will leave this conference understanding and being able to discuss:

- Some practical approaches to compliance and implement as best practices
- Emerging risk-based approaches, including first cycle approval, harmonization and critical path initiatives, and illustrate case studies in adopting these concepts without delaying or disrupting product approvals while increasing supplemental filings
- Integrating quality into the global business platform
- Leveraging results to drive continuous improvement
- Interpreting supply chain and good distribution practices for incoming materials as well as the final product for commercialization
- Defining Quality Systems today as they relate to contract manufacturing.
- Managing product knowledge
- Anticipating emerging regulations
- Responsibilities of the Quality Unit

The *2011 PDA/FDA Joint Regulatory Conference* Steering Committee hopes that you are as excited by the program contents as we are and will take this opportunity to join us to learn and to network with industry and regulatory colleagues new and old, past and present. Please plan to join us in Washington D.C. September 19-23 and learn about current industry trends and how you can become part of the solution to the complex issues facing the industry today.

Sincerely,

Amy Giertych, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*

Susan Schniepp, Vice President of Quality, *OSO BioPharmaceuticals Manufacturing*

Co-Chairs, 2011 PDA/FDA Joint Regulatory Program Planning Committee

Sunday, September 18-Monday, September 19 Agenda

Sunday, September 18, 2011

1:00 p.m. - 6:00 p.m.
Registration Open

3:00 p.m. - 6:00 p.m.
Speaker Ready Room Open

5:00 p.m. - 6:00 p.m.
2011 PDA/FDA Program Planning Committee Meeting

Monday, September 19, 2011

7:00 a.m. - 5:30 p.m.
Registration Open

7:00 a.m. - 8:00 a.m.
New Member Breakfast

7:00 a.m. - 8:30 a.m.
Continental Breakfast

8:15 a.m. - 8:30 a.m.
Welcome, Opening Remarks
Maik W. Jornitz, Group Vice President, *Sartorius Stedim, Inc* and Chair, *PDA Board of Directors*
Richard M. Johnson, President, *PDA*

Amy Giertych, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*
Susan Schniepp, Vice President of Quality, *OSO Biopharmaceuticals Manufacturing*
Co-Chairs, 2011 PDA/FDA Joint Regulatory Conference & TRI Courses Program Planning Committee

8:30 am. - 9:15 a.m.
P1 – Opening Plenary Session
Moderator: Sue Schniepp, Vice President of Quality, *OSO Biopharmaceuticals Manufacturing*

Session Description: This opening plenary provides a unique opportunity to hear the Commissioner (or Commissioner's Office) present the current and future focus of the FDA.

8:30 a.m. - 9:00 a.m.
FDA Representative Invited

9:00 a.m. - 9:15 a.m.
Questions and Answers/Discussion

9:15 a.m. - 10:00 a.m.
Grand Opening of Exhibit Hall and Refreshment Break *(Exhibit hours are 9:15 a.m. - 7:00 p.m.)*

10:00 a.m. - 11:30 a.m.
P2 – Latest News and Inspection Findings in Biotech
Moderator: Rick Friedman, Director, *DMPQ, CDER, FDA*

Session Description: This session will cover recent biotechnology business and regulatory trends and business. FDA representatives will discuss pre-approval inspection trends and case studies. The latest trends in the biotech business will also be covered by a leading pharmaceutical executive.

10:00 a.m. - 10:30 a.m.
Biotech Pre-Approval Inspection Findings
Patricia Hughes, Lead, Consumer Safety Officer, *DMPQ, CDER, FDA*

10:30 a.m. - 11:00 a.m.
Biotech Inspection Trends
Azita Gerhardt, President, Global Pharmaceutical Operations, Abbott Laboratories ***(invited)***

11:00 a.m. - 11:30 a.m.
Questions and Answers/Discussion

11:30 a.m. - 1:00 p.m.
Lunch on your own *(exhibit hall closed)*

"The separate tracks...provided a very broad perspective of the harmonized regulatory landscape and changing conditions...I would deem this conference very beneficial and enlightening."
W. Brown, *Baxter Healthcare Corporation*

Monday, September 19 Agenda (Continued)

1:00 p.m. - 2:30 p.m.
Concurrent Sessions

Foundations	Innovation/Regulatory Science	Quality and Compliance
A1 – OIP 101 & Foreign Inspections **Moderator: Mai Huynh**, Supervisory Team Leader, *CVM, FDA*	**B1 – ICH Q11** **Moderator: Steven Mendivil**, Executive Director, Corporate Quality External Affairs, *Amgen, Inc.*	**C1 – Update on GMP and Quality Guidance** **Moderator: Louise Johnson**, Senior Vice President, Global Development, Quality Assurance, *Takeda Pharmaceuticals*
Session Description: Differentiate the role and function of the foreign offices within FDA's Office of International Programs (OIP) and the role of Office of Regional Operations (Division of Foreign Field Investigations/DFFI) for foreign inspections (for CDER/CVM/CDRH) as well as outline how CBER coordinates its own foreign inspections.	**Session Description:** A discussion of the ICH Q11 step 2 document as it relates and impacts Small Molecule and Biotech APIs. The presentations would include background information on Q11 EWG discussions on key API QbD and Manufacturing topics as they differ from ICH Q8 guidance for drug products.	**Session Description:** As our molecules and supply chains become more complex, global regulations are changing, and rapidly, to provide direction regarding regulatory expectations. Regulators will discuss recently issued regulations and guidelines from around the globe, including highlights on major changes.
1:00 p.m. - 1:30 p.m. **FDA Office of International Program: Foreign Offices: Roles and Responsibilities** **Walter Batts**, International Health Science Program Manager, *OIP, OC, FDA* 1:30 p.m. - 2:00 p.m. **FDA Office of Regulatory Affairs: Division of Foreign Field Investigation: Coordination of Foreign Inspections** **Ann Marie Montemurro**, Director of the Division of Foreign Field Investigations, *ORO, FDA* 2:00 p.m. - 2:30 p.m. **Questions and Answers/Discussion**	1:00 p.m. - 1:30 p.m. **Small Molecule** **Betsy Fritschel**, Director, Corporate Quality, *Johnson & Johnson* 1:30 p.m. - 2:00 p.m. **Biotech Considerations for Q11** **Patrick Swann**, Pharmacologist, *OPS, CDER, FDA* 2:00 p.m. - 2:30 p.m. **Questions and Answers/Discussion**	1:00 p.m. - 1:30 p.m. **Update on GMP and Quality Guidance** **Katrin Nodop**, EMA 1:30 p.m. - 2:00 p.m. **Update on GMP and Quality Guidance** **FDA Representative Invited** 2:00 p.m. - 2:30 p.m. **Questions and Answers/Discussion**

2:30 p.m. - 3:00 p.m.
Refreshment Break in Exhibit Area

3:00 p.m. - 4:30 p.m.
Concurrent Sessions

Foundations	Innovation/Regulatory Science	Quality and Compliance
A2 – First Cycle Review (Part 1) **Moderator: Amy Giertych**, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*	**B2 – Drug Safety** **Moderator: David Cummings**, OPS Quality Program Manager, *FDA*	**C2 – Good Inspection Practices - Domestic** **Moderator: Elizabeth Leininger**, PhD, Regulatory Affairs and Quality Consultant, *E Leininger Consulting, LLC*
Session Description: This session is Part 1 of a two part series. With the goal of achieving a First Cycle Review, the focus will be to lay the framework for the different types of submissions for biologics, drugs and devices and to compare and contrast the submission content. We will discuss reviewer expectations of data quality and provide tips on presenting scientific information in support of the products benefit/risk profile to facilitate a timely review.	**Session Description:** FDA and Industry have common goals that include ensuring access to quality products and protecting public health. Thus, both groups have an increased focus on drug safety. There have been several drugs recently removed from the market due to drug safety issues that were not detected during drug development efforts and were attributed to expanded use in a larger population. Additionally, there have been early communications of drug safety issues resulting in further actions including restricted use, updated product labeling and development of risk evaluation and mitigation strategies (REMS). Safety concerns may arise from a variety of sources including misuse or expanded use of the product, drug-drug interactions, product quality, etc. This session will highlight the importance of evaluating drug safety both during new product development and life cycle management of drugs and biologics.	**Session Description:** In this session, we will explore how regulatory inspections can be a collaborative effort to optimize compliance and overall quallity. • What are today's inspection trends and expections? • How can we improve our current systems and processes by understanding the trends and expectations in today's enforcement environment? • What type of changes are we implementing due to current inspection trends? • What's the cost of inspection readiness? • What types of collaborations and partnerships can impact inspection outcomes?

Monday, September 19 Agenda (Continued)

Foundations	Innovation/Regulatory Science	Quality and Compliance
A2 – First Cycle Review (Part 1) (Continued)	**B2 – Drug Safety (Continued)**	**C2 – Good Inspection Practices - Domestic (Continued)**
	This session will also address the role of pharmacovigilance in drug development and the role of the Office of Safety and Epidemiology in product review and monitoring efforts as well as throughout the product's lifecycle.	
3:00 p.m. - 3:20 p.m. **BLAs and NDAs** **Lina Aljuburi**, Supervisory Consumer Safety Officer, *CDER, FDA* 3:20 p.m. - 3:40 p.m. **PMAs and 510(k)s** **FDA Representative Invited** 3:40 p.m. - 4:00 p.m. **Experience Across All Submission Types** **Lisa Skeens**, Vice President, Global Regulatory Affairs, *Baxter Healthcare Corporation* 4:00 p.m. - 4:30 p.m. **Panel Discussion:** **Lina Aljuburi**, Supervisory Consumer Safety Officer, *CDER, FDA* **Mai Huynh**, Supervisory Team Leader, *CVM, FDA* **Lisa Skeens**, Vice President, Global Regulatory Affairs, *Baxter Healthcare Corporation* **FDA Panelist Representatives Invited**	3:00 p.m. - 3:30 p.m. **Gerald Dal Pan**, Director, *OSE, FDA* ***(invited)*** 3:30 p.m. - 4:00 p.m. **Product Safety Assessments and Surveillance Form Development to Legacy** **John Ayres**, M.D., Senior Director-Global Patient Safety, *Eli Lilly & Company* 4:00 p.m. - 4:30 p.m. **Questions and Answers/Discussion**	3:00 p.m. - 3:30 p.m. **Inspection Opportunities for Collaborations** **John O'Connor**, Senior Director of Corporate Inspection, *Genentech* 3:30 p.m. - 4:00 p.m. **ORO Representative Invited** 4:00 p.m. - 4:30 p.m. **Questions and Answers/Discussion**

4:30 p.m. - 6:00 p.m.
Concurrent Interest Groups

IG1 – Facilities and Engineering / Water Systems Leaders: **Christopher Smalley**, *Merck & Co.* & **Phil DeSantis**, *Merck & Co.*	**Interest Group Description:** The IG1 Session will consist of two topics: "WFI via Reverse Osmosis: Has the Time Come?" and "Green Manufacturing." Each topic will be 30 minutes long and there will be a 30 minute open forum for questions and discussion of items of interest to the attendees.
IG2 – Pre-filled Syringes Leader: **Thomas Schoenknecht**, *SCHOTT*	**Interest Group Description:** The Pre-filled Syringe Interest Group will focus in an open discussion forum style on actual topics related to pre-fillable injection system components for drug delivery such as cartridges or syringes and combinations thereof with injection and safety devices. Latest trends and regulatory requirements for track and trace systems, auto injector requirements on primary containers as well as alternative sterilization methods for material incorporation into isolator systems will be presented and discussed in an open forum. A special focus will be given on recent recalls and their impact on primary packaging material requirements.
IG3 – Packaging Science Leader: **Ed Smith**, *Packaging Science Resources*	**Interest Group Description:** This session will focus on reviewing the key information presented at the *PDA/FDA Glass Quality Conference* in May 2011. Additionally, we will discuss the proposal by USP in PF 37(2) (March 2011) to revise USP ‹660›, Containers-Glass. These proposed changes will bring the USP tests & requirements closer to those in the EP. A review of the important issues from the PQRI Workshop (Feb. 2011) on Extractables and Leachables in Parenteral and Ophthalmic Drug Products (PODP) will also be presented by a member of the PQRI Task Force. Key difference in both the chemical and toxicological aspects of managing PODP versus Inhalation Products will be emphasized. Finally, time will be reserved for an open Q&A period among attendees to discuss current packaging issues.
IG4 – Blow-Fill-Seal/Sterile Processing Leader: **Ken Muhvich**, PhD, *Micro-Relliance, LLC*	**Interest Group Description:** The session will begin with a presentation about the microbial contamination risk for both traditional Blow Fill Seal machines and continuous rotary high speed BFS filling machines. Microbial contamination prevention strategies for both types of BFS machines will be discussed.

Monday, September 19-Tuesday, September 20 Agenda (Continued)

IG5 – Process Validation Leader: **Scott Bozzone**, *Pfizer, Inc.*	**Interest Group Description:** The Process Validation Interest Group Session will include (1) PCMO Initiative on Process Validation and Verification Technical Report Update and Review; (2) Industry reaction and plans for implementation of the 2011 FDA Process Validation Guidance; (3) A discussion of global regulatory trends, inspections and citations related to Process Validation; (4) Report on Interest Group activity and future initiatives, and (5) an Open Forum.
IG6 – Quality Systems Leader: **Anders Vinther**, *Genentech*	**Interest Group Description:** The PDA Quality Systems Interest Group is a network of QA/QC professionals. Past topics have dealt with diverse subjects ranging from Systems Based Inspections, to QA /QC Organizations, to Risk Analysis. The Quality Systems Interest Group also sponsors a Quality Systems Forum on the PDA Web site for daily networking opportunities. Members participate in Task Forces on Compliance and Quality related topics.

6:00 p.m. - 7:30 p.m.
Networking Reception in Exhibit Area

Tuesday, September 20, 2011

7:00 a.m. - 5:30 p.m.
Registration Open

7:00 a.m. - 8:30 a.m.
Continental Breakfast

7:30 a.m. - 8:30 a.m.
Concurrent Breakfast Sessions

Breakfast I – **Quality Risk Map** **Moderator: Sue Schniepp**, Vice President of Quality, *OSO Biopharmaceuticals Manufacturing*	Breakfast II – **ICH Quality - Implementation Working Group Training Outcomes for ICH Q8, Q9 and Q10 and Implications for Future** **Moderator: Jim Lyda**, Senior Director, Regulatory Affairs, *PDA*	Breakfast III – **FDA 101** **Moderator: Adrienne Hornatko-Muñoz**, Consumer Safety Officer, Review Management Staff, *CBER, FDA*	Breakfast IV – **Ask the Regulator: CDER Compliance** **Moderator: Douglas Campbell**, Consumer Safety Officer, *CDER, FDA*
Session Description: This breakfast session will offer a unique opportunity for conference members to hear how one company has successfully adopted the Risk Map approach in their manufacturing operations.	**Session Description:** 2010 was the year for global training on the ICH quality guidelines with international workshops cosponsored between industry and regulators in the three ICH regions: Tallinn, Estonia (organized by PDA), Washington DC and Tokyo. This breakfast session will report on the outcomes of the trainings and the experience gained by the ICH Quality Implementation Working Group (Q-IWG). Deliverables from the trainings and next steps for the ICH Q-IWG will be presented. This will be an open interactive session; so bring any and all of your questions.	**Session Description:** This is your opportunity to become conversant in FDA language and various Center responsibilities for such things as NDAs; BLAs; PMAs; and PAI inspections to name a few. The session will provide an overview of the various Centers within FDA including the Office of Regulatory Affairs and the Office of the Commissioner. Attendees will learn about the human and animal products regulated under FDA Centers. Additionally, attendees will be provided a brief overview other FDA Offices with major roles in the regulatory process such as the Office of the Chief Scientist, Office of Combination Products, Office of Pediatric Therapeutics, the Office of Orphan Drug Designation and the Office of International Programs.	**Session Description:** Attendees will have the opportunity to ask FDA technical and team leaders questions on specific topics during a panel discussion. This breakfast session will provide an excellent opportunity to listen to and directly interact with leaders in the regulatory community on subjects of importance to the pharmaceutical and biopharmaceutical industry.

Tuesday, September 20 Agenda (Continued)

Breakfast I	Breakfast II	Breakfast III	Breakfast IV
7:30 a.m. - 8:00 a.m. **Kimberly Ray**, Senior Manager, Project Management, *OSO Biopharmaceuticals Manufacturing* 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Stephan Roenninger**, PhD, Head of External Relations Europe/Japan, *F. Hoffmann-La Roche Ltd.* 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Lawrence Bachorik**, Assistant Commissioner for External Relations, *OC, FDA* 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:30 a.m. **Panel Discussion** **Tara Gooen**, Team Leader (Acting), New and Generic Drug Manufacturing Team, Office of Compliance, Division of Manufacturing and Product Quality, *CDER, FDA* **Vibhakar Shah**, Compliance Officer/ Chemist, Office of Compliance, Division of Manufacturing and Product Quality, *CDER, FDA*

8:30 a.m. - 10:00 a.m.
P3 – Recall Lessons
Moderator: John Finkbohner, PhD, Senior Director, Regulatory Affairs/Vaccines, *MedImmune, LLC*

Session Description: The heightened visibility of recalls in the past year has highlighted the need for having a robust process for handling recall actions. Recalls demand not only significant pre-planning to ensure efficient operation of the quality unit, but also well-defined processes for materiel handling and communicating with stakeholders (government agencies, consumer protection groups, and consumers). We will explore some of these dynamics in this plenary session with an emphasis on highlighting lessons that can be learned from the recall experience of the overall manufacturing sector in the recent past.

8:30 a.m. - 8:50 a.m.
Broad Challenges in Implementing Recall
Dirk Gibson, PhD, Associate Professor of Communication and Journalism, *University of New Mexico*

8:50 a.m. - 9:10 a.m.
Hands on Challenges - Regulatory Perspective
FDA Representative Invited

9:10 a.m. - 9:30 a.m.
Hands on Challenges - Industry Perspective
Raymond Godlewski, Vice President, Quality and Compliance, *MedImmune LLC*

9:30 a.m. - 9:45 a.m.
Trending
Karthik Iyer, Consumer Safety Officer, *DMPQ, CDER, FDA*

9:45 a.m. - 10:00 a.m.
Questions and Answers/Discussion

10:00 a.m. - 4:15 p.m.
Exhibit Hall Open

10:00 a.m. - 10:45 a.m.
Refreshment Break in Exhibit Area

Tuesday, September 20 Agenda (Continued)

10:45 a.m. - 12:15 p.m.
Concurrent Sessions

Foundations	Innovation/Regulatory Science	Quality and Compliance
A3 – First Cycle Review (Part 2) **Moderator: Laurie Norwood**, Deputy Director, *DMPQ, FDA*	**B3 – Accountability in a Global Environment – (Enforcement and Supply Chain)** **Moderator: Tim Tomkovich**, QA Director, *Abbott Global Pharmaceutical Operations*	**C3 – FDA Accession to PIC/S** **Moderator: Jim Lyda**, Senior Director, Regulatory Affairs, *PDA*
Session Description: First Cycle Approval Part 2: How do you reach success the first time around when submitting an application or manufacturing supplement to the Agency? This session will focus on the Top Ten reasons why it is possible to **miss the mark** or **make the mark** on a first cycle approval. This session will concentrate on the review as well as inspectional/compliance issues that lead to desirable and undesirable outcomes. In this session learn from the FDA, the "Top Ten," and hear from industry, their real life experiences of missing and making the mark.	**Session Description:** The Pharmaceutical world is shrinking with the onset of harmonization. Regulators, companies and suppliers must learn to operate in a more global environment and take accountability for their decision making processes and activities from beginning to end. This session will explore how various sectors of the pharmaceutical industry have adapted to the emerging global culture.	**Session Description:** On January 1, 2011, FDA joined the Pharmaceutical Inspection Co-operation Scheme (PIC/S). PIC/S, based out of Geneva, is an international organization for pharmaceutical inspectorates which fosters cooperation in development, training and interpretation of pharmaceutical Good Manufacturing Practices (GMP). PIC/S promotes harmonized GMP standards and guidance's and has a program for assessing the inspectorates of member countries. In recent years, significant changes to GMP have been developed thru PIC/S initiatives (e.g. ICH Q7a) and it is anticipated that the membership of FDA will strengthen this role. This session will provide an overview of FDA's perspectives on membership in PIC/S, including FDA goals and next steps in collaboration. In addition, there will be an industry perspective on possible benefits and opportunities as a result of the 'new' PIC/S.
10:45 a.m. - 11:05 a.m. **Industry Case Study** **FDA Representative Invited** 11:05 a.m. - 11:25 a.m. **Industry Case Study** **Darrin Cowley**, PhD, Director Product Quality, *Amgen, Inc.* 11:25 a.m. - 11:45 a.m. **Industry Case Study** **Amy Giertych**, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation* 11:45 a.m. - 12:15 p.m. **Panel Discussion:** **FDA Representatives Invited** **Darrin Cowley**, PhD, Director Product Quality, *Amgen, Inc.* **Amy Giertych**, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*	10:45 a.m. - 11:15 a.m. **FDA Representative Invited** 11:15 a.m. - 11:45 a.m. **Quality Systems Perspective from a CMO** **Sue Schniepp**, Vice President of Quality, *OSO Biopharmaceuticals Manufacturing* 11:45 a.m. - 12:15 p.m. **Questions and Answers/Discussion**	10:45 a.m. - 11:15 a.m. **PIC/S + FDA: Impact and Opportunity** **Stephan Roenninger**, PhD, Head of External Relations Europe/Japan, *F. Hoffmann-La Roche Ltd* 11:15 a.m. - 11:45 a.m. **FDA's Entry into PIC/S: A Strategic Collaboration** **Brenda Holman**, Executive Director, ORA Strategic Initiatives, *ORA, FDA* 11:45 a.m. - 12:15 p.m. **Questions and Answers/Discussion**

12:15 p.m. - 1:15 p.m.
Lunch on your own

Tuesday, September 20 Agenda (Continued)

1:15 p.m. - 2:45 p.m.
Concurrent Sessions

Foundations	Innovation/Regulatory Science	Quality and Compliance
A4 – Standards **Moderator: David Cummings**, OPS Quality Program Manager, *FDA*	**B4 – GMP by Life Cycle Phase** **Moderator: Vince Mathews**, Quality Assurance Consultant, *Eli Lilly & Company*	**C4 – International Compliance Update** **Moderator: Douglas Campbell**, Consumer Safety Officer, *CDER, FDA*
Session Description: There are many definitions for the term standard. The American Society for Quality defines a standard as the metric, specification, gauge, statement, category, segment, grouping, behavior, event or physical product sample against which the outputs of a process are compared and declared acceptable or unacceptable. The White House Office of Management and Budget defines a standard, in part, as common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices. FDA regulated products (e.g., biologics, drugs, devices, and combination products) are impacted by a number of different types of standards, including voluntary and consensus standards. This session will address standards employed by FDA and industry and provide for dialogue on standards development opportunities and application for products regulated by CBER, CDER, CVM and CDRH.	**Session Description:** It is important to ensure quality and patient safety during all phases of the product lifecycle. However, there are several factors that vary during the product lifecycle that should be considered when determining appropriate controls that should be in place during these various phases. Some of the considerations include: • Type of drug product • Phase of development • Scale of operation • Regulations In this session, it will demonstrate how appropriate controls for the manufacture of drugs can be determined despite the complexity of how these and other factors can interact to affect drug quality and patient safety.	**Session Description:** During FY 2010, there was an increase in enforcement as a result of manufacturing problems unidentified during international CGMP inspections. This session will provide highlights from FDA's international surveillance, review trends, and discuss case studies.
1:15 p.m. - 1:25 p.m. **Jon Clark**, Associate Director for Policy, *CDER, FDA* 1:25 p.m. - 1:35 p.m. **Carlos Peña**, Senior Science Policy Advisor, *OC, FDA* 1:35 p.m. - 1:45 p.m. **Chris Joneckis**, Senior Advisor for CMC Issues, *CBER, FDA* 1:45 p.m. - 1:55 p.m. **Charles O'Brien**, Team Leader, *CVM, FDA* 1:55 p.m. - 2:05 p.m. **Scott Colburn**, Deputy Director of the Standards Program, *CDRH, FDA* 2:05 p.m. - 2:45 p.m. **Panel Discussion/Questions and Answers**	1:15 p.m. - 1:35 p.m. **How a Virtual Company makes Clinical Trial Material - From a Quality System and GMP Perspective** **Elizabeth Leininger**, PhD, Regulatory Affairs and Quality Consultant, *E Leininger Consulting* 1:35 p.m. - 1:55 p.m. **Application of Phase-Appropriate CGMP and Quality Systems to the Development of Protein Bulk Drug Substance – from R&D thru Phase 3 Clinical Trials** **Amnon Eylath**, PhD, Director of Quality, *Ariad Pharmaceuticals* 1:55 p.m. - 2:15 p.m. **Quality Systems Appropriate for the Preparation of Early Phase Clinical Supplies** **Richard Hoffman**, Principal Consultant - Regulatory, *Eli Lilly & Company* 2:15 p.m. - 2:45 p.m. **Questions and Answers/Discussion**	1:15 p.m. - 1:35 p.m. **FY 10 International Post Approval Inspection Surveillance Review** **Diane Alexander**, Chief, Biological Drug and Device Compliance Branch, *CBER, FDA* 1:35 p.m. - 1:55 p.m. **CDER Update** **FDA Representative Invited** 1:55 p.m. - 2:15 p.m. **CDRH Update** **FDA Representative Invited** 2:15 p.m. - 2:45 p.m. **Panel Discussion/Questions and Answers**

2:45 p.m. - 3:15 p.m.
Refreshment Break in Exhibit Area

Tuesday, September 20 Agenda (Continued)

3:15 p.m. - 4:45 p.m.
Concurrent Sessions

Foundations	Innovation/Regulatory Science	Quality and Compliance
A5 – WHO Update **Moderator: Maria Guazzaroni Jacobs**, PhD, Director, Quality and Regulatory Policy, *Pfizer, Inc.*	**B5 – Regulatory Science** **Moderator: Rich Levy**, PhD, Senior Vice President, Science and Regulatory Affairs, *PDA*	**C5 – Supply Chain** **Moderator: Barbara Zinck**, President, *Zinck Consulting*
Session Description: The development of standards and guidelines to promote quality assurance is an integral part of WHO's Constitution. Important key elements are quality assurance guidances in the areas of production, testing, and distribution of medicines, such as GMPs, GDPs, prequalification of medicines, International Nonproprietary Names (INNs), etc., intended for use by national regulatory authorities, manufacturers, and others. This session will present an update on the activities of the WHO Office of Quality Assurance & Safety: Medicines, as well as an industry perspective on the benefits and challenges in the application of the WHO guidelines.	**Session Description:** FDA Strategic Priorities 2011-2015 Responding to the Public Health Challenge of the 21st Century outlines the Commissioner's four cross-cutting areas and serves as a road map over the next five years. These include efforts to: 1) Advance Regulatory Science and Innovation; 2) Strengthen the Safety and Integrity of the Global Supply Chain; 3) Strengthen Compliance and Enforcement Activities to Support Public Health; and 4) Address the Unmet Public Health Needs of Special Populations. The strategic plan for advancing regulatory science will pave the way for a range of regulatory activities, including setting standards for products that address unmet public health needs, identifying and mitigating the spread of disease using informatics, modernizing toxicology and hazard assessments, protecting the food supply, and regulating tobacco. The plan will enable FDA to leverage the latest in science and technology, along with FDA know-how, to bring a new generation of medical products—personalized therapies, stem-cell therapies, and genetic diagnostics, among others—to the American people. Before FDA can make a decision to approve a new product, we must determine what it means for that product to be safe and effective. We must develop the appropriate standards and guidance for making approval decisions. The science, the tools, and the standards we need to assess and evaluate the efficacy, quality, and performance of a food or medical product form what is *regulatory science*. This session will feature an overview of regulatory science related to areas of pharmaceutical, laboratory and manufacturing sciences.	**Session Description:** CDER's Office of Compliance (OC) has targeted supply chain security as one of its top priorities this year. There are risks to the security, safety, availability and serious challenges inherent in the global pharmaceutical supply chain that can harm patients and hurt companies. Many, including the FDA, have stated that industry needs better systems in place for safeguarding its products and must start thinking about where the gaps are and what is missing in its supply chain controls. "The biggest risk is the risk we haven't thought of." This Supply Chain session will present case studies with tangible solutions for securing global pharmaceutical supplies.
3:15 p.m. - 3:45 p.m. **WHO Update from the Office of Quality Assurance & Safety: Medicines** **Sabine Kopp**, PhD, Quality Assurance and Safety: Medicines, Medicines Policy and Standards, *World Health Organization* 3:45 p.m. - 4:15 p.m. **WHO Prequalification Program and WHO Guidelines – An Industry View** **Aileen Fisher**, Emerging Markets CMC, Global CMC, Pharmaceutical Sciences, *Pfizer Inc.* 4:15 p.m - 4:45 p.m. **Questions and Answers/Discussion**	3:15 p.m. - 3:45 p.m. **Vicki Seyfert-Margolis**, PhD, *OC, FDA* 3:45 p.m. - 4:15 p.m. **Yvonne Stewart**, PhD, Head of External Advocacy, Quality Centre of Excellence Global Manufacturing & Supply, *GlaxoSmithKline* ***(invited)*** 4:15 p.m - 4:45 p.m. **Questions and Answers/Discussion**	3:15 p.m. - 3:45 p.m. **EFPIA European Vision: Fighting Counterfeiting With Serialization** **Claire Barber**, Head of Global Product Security, *AstraZeneca UK Limited* 3:45 p.m. - 4:15 p.m. **Supply Chain Management** **Steven Wolfgang**, Team Leader for the Data Analysis Team, *CDER, FDA* **CDRH Speaker Confirmed** 4:15 p.m - 4:45 p.m. **Questions and Answers/Discussion**

Tuesday, September 20-Wednesday, September 21 Agenda (Continued)

4:45 p.m. - 6:15 p.m.
Concurrent Interest Groups

IG7 – Combination Products Leader: **Michael Gross**, *Biologics Consulting Group*	**Interest Group Description:** This interest group provides a forum for discussion of topical issues concerning submissions and compliance matters related to a variety of combination product types with emphasis on drug delivery devices and functional pharmaceutical packaging. The format of the Combination Products Interest Group meetings includes open discussions of hot topics and formal presentations by industry and government experts on a variety of topical combination product quality and regulatory issues.
IG8 – Supply Chain Management Leader: **Lucy Cabral**, *Genentech*	**Interest Group Description:** Suppliers of raw and manufactured materials to biotech and pharmaceutical companies, as well as those drug manufacturers, are challenged with an increasing complexity of the material supply chain. This has in turn led to increasing difficulty in ensuring quality supply of materials and components, excipients, and APIs. Furthermore, the integrity of the supply chain is being challenged by increasing sub-standard manufacturing, inadequate business and process controls, as well as international counterfeiting practices. The Supply Chain Management Interest Group offers its members the opportunity to influence the suppliers of the pharmaceutical and biotech industry to develop requirements that meet the needs of the industry in the areas of material quality, continuous improvement efforts, supply chain security, and supplier/customer business partnerships. The Interest Group will use existing information gathered from PDA members, suppliers, other industry groups, and drug manufacturers to document and develop best practices approach for suppliers to meet customer requirements globally.
IG9 – Regulatory Affairs Leader: **Amy Giertych**, *Baxter Healthcare Corporation*	**Interest Group Description:** The PDA Regulatory Affairs Interest group provides a discussion forum for topics and issues related to North American Regulatory Affairs. These topics can include issues in Quality by Design (QbD), biosimilars, and regulations related to Combination Products. The Regulatory Affairs Interest Group may interact and collaborate with global regulatory agencies to include WHO, MHRA, and EMA. Topics on the establishment and bridging of reference standards, stability and stability testing studies, and extractables and leachable studies for both drug substance and drug product may be included as feature topics for an Interest Group session at one or more of PDA's signature meetings.
IG10 – Clinical Trial Materials Leader: **Vince Mathews**, *Eli Lilly & Company*	**Interest Group Description:** The Clinical Trial Materials Interest Group offers members an opportunity to discuss topics of interest associated with the development and manufacture of clinical supplies. This includes the pre-clinical phase (involving pharmaceutical development operations), the manufacture of all phases of clinical supplies (including both API and drug product), and the ultimate transfer of the manufacturing process to the commercial manufacturing site. This group offers a valuable opportunity to interact with professionals and regulators alike to share ideas, discuss opinions, and offer advice to each other in this very complex area of the pharmaceutical business. When deemed appropriate by the group, position papers may be drafted and feedback on proposed regulations may be given.
IG11 – Lyophilization/ Visual Inspection Leader: **Edward Trappler**, *Lyophilization Technology, Inc.* & **John Shabushnig**, PhD, *Pfizer*	**Interest Group Description:** The Visual Inspection of Parenterals Interest Group provides a forum to discuss topics related to the visual inspection of injectable products. A brief update on recent regulatory activity in the area will be presented. This will be followed by a discussion on topics of interest as chosen by those in attendance. Past topics have included selection and qualification of human inspectors, validation of automated inspection systems, inspection of difficult products or packages and country specific inspection requirements.
IG12 – Risk Management Leader: **Mike Long**, *ValSource, LLC*	**Interest Group Description:** The session will focus on facilitated breakout sessions to review and discuss the PCMO Case studies and TR 44 Volumes 1 & 2. The interactive sessions will allow participants the opportunity to ask questions, discuss how these draft reports may be useful to their organizations and provide input. Lead or members of the authoring Teams will participate in these breakout sessions.
IG13 – Vaccines Leader: **Frank Kohn**, *FSK Associates, Inc.*	**Interest Group Description:** Update on Vaccine QbD Case Study. A consortium of vaccine industry representatives are developing a case study exercise in collaboration with FDA and EMA to promote adoption and enable implementation of QbD concepts in vaccine development. The final draft of the study guide for this project is scehduled for release in the Fall of 2011. This session is intended to share experiences from gained through this process and to provide attendees with an update on the outcomes of the project to date.

6:30 p.m. - 9:30 p.m.
Gala Reception

Wednesday, September 21, 2011

7:00 a.m. - 12:00 p.m.
Registration Open

7:00 a.m. - 8:30 a.m.
Continental Breakfast

Wednesday, September 21 Agenda (Continued)

7:30 a.m. - 8:30 a.m.

Concurrent Breakfast Sessions

Breakfast V – **Paradigm Change in Manufacturing Operations (PCMO) – Risk Based Manufacturing** **Moderator: Veronique Davoust,** Manager, Global Quality Strategy, *Pfizer Global Manufacturing*	Breakfast VI – **The Qualified Person** **Moderator: Susan Schniepp,** Vice President of Quality, *OSO Biopharmaceuticals Manufacturing*	Breakfast VII – **Biotech Multi-Product Facilities** **Moderator: Tim Tomkovich,** QA Director, *Abbott Global Pharmaceutical Operations*	Breakfast VIII – **Type C Meeting** **Moderator: David Doleski,** Team Leader, NGDMT 3, *DMPQ, CDER, FDA*	Breakfast IX – **Process Validation** **Moderator: Douglas Campbell,** Consumer Safety Officer, *CDER, FDA*
Session Description: This session will report and discuss two deliverables of the Paradigm Change in Manufacturing Operations (PCMO) project: a) statistical tools for manufacturing and b) case studies on implementation of QRM in manufacturing operations. The interactive discussion allows participants to address questions and provide input.	**Session Description:** This breakfast session will offer a unique opportunity for conference members to hear about the Qualified Person program in Europe from a practicing QP.	**Session Description:** The development of a multi-product biotechnology facility can present unique technical, regulatory and compliance requirements to achieve successful registration and approval of the site. The session will focus on challenges that can be encountered as well as potential available solutions to meet the global regulatory and compliance expectations relating to biotech product production in a multi-product facility.	**Session Description:** Sponsors may request Type C meetings related to the development of PDUFA products. These meetings present an opportunity for sponsors to describe plans for the design of new manufacturing facilities, modification of existing facilities, changes in manufacturing locations, modifications in the manufacturing processes, equipment qualification and process validation, among other topics. Receiving Agency feedback early in the early stages of a project can be advantageous in that potential Agency concerns are identified prior to the review and/or the pre-approval inspection process. A CBER representative can share experiences based on numerous Type C meetings with industry. Expectations for preparing meeting briefing packages and framing questions will be provided. The anticipated outcome is that sponsors can learn how to maximize the effectiveness of these meetings in order to obtain critical feedback early in the project planning stages.	**Session Description:** FDA published the final version of their Process Validation Guidance in January 2011. The guidance represents a significant change in approach from the prior 1987 guidance on the same subject. This session will feature invited representatives from FDA and the industry, each of whom will provide their perspective on the approaches outlined in the guidance and their experiences with implementation since the guidance was published. A short question and answer session will follow.
7:30 a.m. - 7:50 a.m. **PCMO Report: Utilization of Statistical Methods for Production & Business Processes** **Greg Flexman,** Process and Risk Analysis, *Talecris* 7:50 a.m. - 8:10 a.m. **QRM Case Studies** **William Harclerode,** Assistant Director, Quality Risk Management, *Forest Labs* 8:10 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Claudio Puglisi,** Technical Director - Qualified Person, *Magis Farmaceutici S.p.A* 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Kristin Murray,** Sr. Manager Regulatory Compliance, *Pfizer, Inc.* 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Effective Use of Type C Meetings with FDA** **FDA Representative Invited** 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**	7:30 a.m. - 8:00 a.m. **Panel Discussion** **Scott Bozzone,** PhD, Senior Manager, Global QO Validation, *Pfizer, Inc.* **FDA Representative Invited** 8:00 a.m. - 8:30 a.m. **Questions and Answers/Discussion**

Wednesday, September 21 Agenda (Continued)

8:45 a.m. - 10:15 a.m.
P4 – Compliance Update
Moderator: Robert Dana, Senior Vice President, Regulatory Affairs and PDA Training and Research Institute, *PDA*

Session Description: This session will feature the Compliance Directors from the FDA Centers (CBER, CDER, CDRH and CVM), as well as the Office of Regulatory Affairs (ORA). Each of the Directors will provide their perspective on current compliance issues affecting the manufacture, testing and distribution of biopharmaceutical products, active drug substances and drug products and medical devices and combination products. Following a brief presentation by each of the five participants, there will be ample time for a Q and A session, where the presenters will take and respond to questions from the floor. This session is always a Conference highlight; come prepared with your questions and don't miss this great opportunity to hear the latest in the compliance area.

Panel Participants:
CBER: Mary Malarkey, Director, Office of Compliance and Biologics Quality, *CBER, FDA*
CVM: Eric Nelson, Director, Division of Compliance, *CVM, FDA*
CDRH: Steve Silverman, Director, Office of Compliance, *CDRH, FDA*
CDER: Rick Friedman, Director, *DMPQ, CDER, FDA*
CDER: Ilisa B.G. Bernstein, Pharm.D., J.D., Deputy Director, Office of Compliance, *CDER, FDA*
ORA: Howard Sklamberg, Director, Office of Enforcement, *ORA, FDA*

10:15 a.m. - 10:45 a.m.
Refreshment Break

10:45 a.m. - 12:15 p.m.
P5 – Center Initiatives
Moderator: Amy Giertych, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*

Session Description: In this session we will hear directly from some of the agency's leaders with regard to their Center's current and future initiatives. Leaders from CBER, CDER, CDRH, CVM and ORA have confirmed their participation in this important discussion.

Panel Participants:
CDRH: Steve Silverman, Director, Office of Compliance, *CDRH, FDA*
CBER: Christopher Joneckis, Senior Advisor for CMC Issues, CBER, *FDA*
CVM: Bernadette Dunham, Director, *CVM, FDA*
CDER: Janet Woodcock, Director, *CDER, FDA*
ORA: Howard Sklamberg, Director, Office of Enforcement, *ORA, FDA*

12:15 p.m.
Closing Remarks and Adjournment
Amy Giertych, Senior Director, Global Regulatory Affairs, *Baxter Healthcare Corporation*
Susan Schniepp, Vice President of Quality, *OSO Biopharmaceuticals Manufacturing*
Co-Chairs, 2011 PDA/FDA Joint Regulatory Program Planning Committee

Continuing Education

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Following full attendance, completion and submission of the appropriate evaluation forms, certificates will be mailed within four to six weeks of the event. Continuing Education Units (CEUs) will be awarded as follows:

2011 PDA/FDA Joint Regulatory Conference & TRI Courses

ACPE #0116-9999-11-029-L04-P | 1.475 CEUs
Type of Activity: Knowledge

For course CEUs and ACPE information for individual courses, see pages 14-17.

Learning Objectives

At the conclusion of this conference, you will be able to:

- Administer practical approaches to compliance that industry can implement as best practices in their companies
- Discuss emerging risk-based approaches, including first cycle approval, harmonization and critical path initiatives and illustrate case studies in adopting these concepts without delaying or disrupting product approvals while increasing supplemental filings
- Integrate quality into the global business platform
- Leverage results to drive continuous improvement
- Interpret supply chain and good distribution practices for incoming materials as well as the final product for commercialization
- Define quality systems today as they relate to contract manufacturing
- Manage product knowledge through product transfer activities
- Anticipate emerging regulations
- Summarize foreign inspections practices and expectations from foreign regulators
- Describe basic principles of New ICH Paradigm
- Identify the basic principles of the FDA Quality Systems including:
  - CAPA
  - Managing Regulatory Inspections
  - Root Causes for Product Recalls
  - Responsibilities of the Quality Unit

Who Should Attend

Departments: Research & Development | Regulatory Affairs | Manufacturing | Quality Assurance/Control | Marketing | Sales

Job Functions: Supply Chain | Clinical Supply Material Preparation | Executive Management

TRI Training Courses - September 22-23, 2011

In conjunction with the *2011 PDA/FDA Joint Regulatory Conference & TRI Courses*, the PDA Training and Research Institute (PDA TRI) is offering seven stand-alone courses related to the latest technologies, newly-enacted regulations and updated processes in the pharmaceutical and biopharmaceutical industries. **All courses will be held on September 22-23 from 8:30 a.m. – 4:00 p.m. at the Renaissance Hotel in Washington, D.C.**

Effective Investigations and Corrective Actions

September 22, 2011, 8:30 a.m. – 4:30 p.m.
PDA #167 | ACPE #0116-0000-09-167-L04-P | 0.6 CEUs
Type of Activity: Knowledge, Application

Course Description

This course evaluates the current GMP requirement to investigate failure and examines whether or not companies' current methods of performing investigations are meeting the regulatory requirements and improving operations. Effective investigation techniques will be covered; attendees will know what is expected from a proper investigation and how to efficiently perform a CAPA investigation in a way that meets FDA requirements and benefits the company. This course teaches tools and techniques that can be employed to get to the root causes of unexpected quality events, resolving them in a lasting, GMP compliant manner. Participants will examine actual situations, guiding them to effective investigation resolution and determining solutions to effect proper corrective action.

Who Should Attend

This course is designed for quality managers, auditors, production managers and top management interested in learning the value of good investigations, as well as how to enhance the QA investigative function as a valuable cost-savings and quality-improvement tool. Consultants, auditors and government inspectors will find this course particularly useful in enhancing their inspections and capabilities.

Learning Objectives

Upon completion of this course, you will be able to:

- Discuss what an effective investigation is and what it is not
- Apply tools that will allow the company to rapidly determine the root causes of deviations, problems and failures
- Implement a sound and effective CAPA program
- Examine tools to use in different situations and how to sell management on effective corrective action and implementation
- Perform effective and valid investigations
- Utilize the tools taught in this course to incorporate cost-saving methodologies into your company's failure investigations

Instructor

Michael Anisfeld, President, *Globepharm Consulting, Inc.*

Quality by Design for Biopharmaceuticals: Concepts and Implementation

September 22, 2011, 8:30 a.m. – 4:30 p.m.
PDA #376 | ACPE #0116-0000-09-376-L04-P | 0.6 CEUs
Type of Activity: Knowledge, Application

Course Description

This course aims to clarify the key concepts that interplay in defining and implementing QbD towards manufacturing of biotech products. This will be achieved via a sequence of lectures and group work. Concepts discussed include: Critical Quality Attributes (CQA), Design Space, Risk Assessment, Control Strategy, Process Analytical Technology, Process Validation, Process Monitoring and QbD Filing. At the end of the course, the audience will be able to explain what these concepts mean, the role they play in QbD implementation and the interplays amongst them.

Who Should Attend

Individuals who are involved in product and process development in the biotech industry. Attendees from academia and regulatory agencies may also benefit depending on their areas of interest and level of experience.

Prerequisites

Participants should have a basic understanding of GMP manufacturing and commercialization lifecycle of a biotech product.

Learning Objectives

Upon completion of this course, you will be able to:

- Discuss several QbD concepts such as Critical Quality Attributes (CQA), Design Space, Risk Assessment, Control Strategy, Process Analytical Technology, Process Validation, Process Monitoring and QbD Filing.
- Define CQAs and explain the link between CQAs and Design Space
- Describe what you need to do differently in your present job in the QbD paradigm
- Explain the role of PAT in QbD paradigm
- Discuss the challenges of implementing QbD
- Explain the role of Risk Assessment and where to find the appropriate tool
- Describe how QbD can be implemented for commercialization of biotech products

Instructors

Anurag Rathore, PhD, Consultant, Biotech CMC Issues Faculty Member, *Department of Chemical Engineering, IIT Delhi, India* & **Patrick Swann**, PhD, Deputy Director, Division of Monoclonal Antibodies, *OBP-OPS-CDER, FDA*

TRI Training Courses - September 22-23, 2011 (Continued)

Active Pharmaceutical Ingredients - Manufacture & Validation

September 22-23, 2011, 8:30 a.m. – 4:30 p.m.
PDA #175 | ACPE #0116-0000-10-175-L04-P | 1.2 CEUs
Type of Activity: Knowledge, Application

Course Description

This is an in-depth, two-day workshop designed to give the participant a thorough foundation in manufacturing operations related to the production of active pharmaceutical ingredients (API). It is a course on how to operate an API plant. All aspects of plant operations are covered, including how to manage the relationship with the regulatory authorities. Four sets of competencies are covered:

The Drug Regulatory and Compliance Process: API operations in a pervasively regulated environment & Q7, personnel training and certification, process development strategy, master records and batch records, and changes to approved filings

Operations: Plant controls, product reprocessing, parenteral and sterile grade APIs, and API impurity profiles

Validation: Technical transfers, equipment qualification, process validation, cleaning validation, computer validation, computer systems validation, water systems design and validation

FDA Inspections: Legal authority of the FDA to investigate drug substance operations, preparation for an inspection, inspector authority vs. company rights, exit interviews, and legal action against noncompliance

Who Should Attend

Personnel in Manufacturing, Validation, Quality Assurance, and Quality Control.

Learning Objectives

Upon completion of this course, you will be able to:

- Discuss the regulatory and compliance issues associated with the manufacture of API
- Analyze and improve the organization of their process development, personnel training and manufacturing programs
- Demonstrate use of several tools to formulate the validation programs commonly required for the manufacture of APIs
- Describe the regulatory and compliance interfaces surrounding and controlling API manufacturing operations.

Instructor

Daniel H. Gold, PhD, President, *D.H. Gold Associates, Inc.*

Documenting and Conducting OOS Investigations

September 22-23, 2011, 8:30 a.m. – 4:30 p.m.
PDA #365 | ACPE #0116-0000-09-365-L04-P | 1.2 CEUs
Type of Activity: Knowledge, Application

Course Description

In an FDA regulated environment, accurate and thorough investigation is a critical response for out of specification (OOS) laboratory test results. The challenge is to capture necessary information in a timely fashion from a diverse workforce of individuals with technical and non-technical backgrounds. This course provides a process to overcome that challenge, integrating FDA requirements and guidelines that focus on effective documentation, data collection, and the understandable language necessary for successful investigations.

Who Should Attend

This course is appropriate for quality team professionals in the pharmaceutical industry, as well as those who are regularly called upon to resolve problems or whose input would aid in preventing problems. Engineers, quality assurance/quality control personnel, upper level management and operational supervisors will benefit from this course.

Learning Objectives

Upon completion of this courses, participants will be able to:

- Discuss the FDA's requirements and expectations of how to conduct and document an OOS investigation
- Explain the roles of various team members in the investigation and documentation process
- Identify data collection techniques and how to separate the "knowns" from the "unknowns"
- Describe techniques and methodology to identify root cause and the necessary corrective and preventive action
- Prepare appropriate and concise documentation of investigation results that adheres to FDA requirements
- Illustrate how to improve communication and teamwork within the quality department to prevent OOS recurrence

Instructor

Nate Conover, Senior Partner, *Pathwise*

TRI Training Courses - September 22-23, 2011 (Continued)

Preparing for Regulatory Inspections for the FDA and EMA

September 22-23, 2011, 8:30 a.m. – 4:30 p.m.
PDA #308 | ACPE #0116-0000-11-308-L04-P | 1.2 CEUs
Type of Activity: Knowledge, Application

Course Description

As the FDA continues to perform GMP and Pre-Approval Inspections, the EMA has become very active in performing "foreign" GMP and Pre-approval inspections at manufacturing sites in the US and other non-EU countries as well. The objective of this two-day lecture course is to assist participants in the preparation of hosting an inspection, primarily focusing on EMA GMP or pre-approval site inspections. The presentation will cover background information on the EU and FDA, the EU GMP Rules, and current FDA inspection initiatives. Also, discussions will include the EMA inspectorate, inspection techniques and methodologies used.

Who Should Attend

This course is designed for Manufacturing, Regulatory and Quality Personnel involved in hosting and managing an EMA or FDA site inspection.

Learning Objectives

Upon completion of this courses, the participant will be able to:

- Discuss background information regarding the EU, EU governing documents, GMP rules, and the EMA
- Identify the inspection techniques and methodologies used by the EMA inspectorate
- Discuss and apply the EU GMP rules – Eudralex Volume 4 and Annexes and other guidance documents that impact inspections
- Discuss strategies for hosting and managing FDA and EMA inspections
- Compare and contrast FDA and EMA inspections
- Create resolutions to a variety of issues that may arise during an inspection

Instructor

David Chesney, VP, Strategic Compliance Services, *PAREXEL Consulting*

Role of the Quality Professional in the 21st Century

September 22-23, 2011, 8:30 a.m. – 4:30 p.m.
PDA #410 | ACPE #0116-0000-10-410-L04-P | 1.2 CEUs
Type of Activity: Knowledge, Application

Course Description

Today the quality professional makes his contribution to the success of the enterprise by fulfilling the roles of quality improver; i.e., process/systems improver and quality promoter. The responsibility for quality control and compliance is not the prime responsibility of the quality professional but the responsibility of everyone, meaning all the performers of product related tasks, whether in the lab or in production. We envision a new and much more proactive and exciting role for the quality professional than in the past. This course will not only describe this new role, its importance and relationship to other groups in the company, but will also provide opportunities to learn and practice new skills which include process/systems design, evaluation and management, risk analysis, promotion of quality, change management, quality planning, quality costs and metrics, and useful quality tools.

Who Should Attend

Quality professionals in the pharmaceutical, medical device and related industries, in either a plant environment or in research.

Prerequisites

The prior reading of ISO 9000 and recent documents on Quality Systems and Risk management is useful. An open mind, desire to contribute and learn are essential.

Learning Objectives

At the completion of this course, you will be able to:

- Construct a new and more proactive role so that your organization can meet the evolving challenges facing the pharmaceutical industry
- Implement the skills learned in the course that enable you to fulfill this new role

Instructor

Robert Kieffer, *RGK Consulting*

Please see the registration form for PDA Training and Research Institute (PDA TRI) Course fees.

TRI Training Courses - September 23, 2011 (Continued)

GMPs for Manufacturers of Sterile and/or Biotechnology Products

September 23, 2011, 8:30 a.m. – 4:30 p.m.
PDA #242 | ACPE #0116-0000-09-242-L04-P | 0.6 CEUs
Type of Activity: Knowledge, Application

Course Description

The manufacture of sterile drug and biotechnology products technologically represents the hardest challenge for the pharmaceutical manufacturer to perform correctly. Sterile dosage form manufacture has no margin for error – a microbially contaminated product can kill the patient. The challenges for the pharmaceutical and biotechnology industries are to design the facility, equipment, and processes in order to prevent the ingress of microbial containments and to build systems that guarantee products made are sterile. Participants will understand how they are the largest source of product contamination and how their behavior has direct impact on product safety.

This course discusses the practical implementation of GMPs in facility and equipment design, in process design and operations. Participants will leave with an understanding of the microbiology of bacteria and their lethality, the regulatory expectations of equipment and utility qualification and sterile process validation in order to assure that the products manufactured are proof-positive sterile.

Who Should Attend

This course is designed as an intermediate level course for supervisors and managers needing to understand the theoretical and practical background for the successful manufacture of sterile pharmaceutical and biotechnology products. Production, Engineering, Regulatory and especially Quality Assurance staff will benefit from this course. The practical examples of industry successes and failures will provide practical examples of what attendees should and should not do in their facilities to manufacture sterile products.

Learning Objectives

Upon completion of this courses, participants will be able to:

- Explain how bacteria and viruses live and die
- Describe the unique concerns for biotechnology facility design
- Summarize requirements, installation issues, and qualification of HVAC Systems, Water Systems, and Compressed Air and Nitrogen Systems
- Discuss terminal sterilization technologies, such as designing sterilization cycles, theoretical and practical considerations in sterilization processes, depyrogenation issues, and the essential differences between designing and operating a facility for terminal sterilization and for aseptic processes.
- Identify the challenges of aseptic processing in the manufacture of sterile and/or biotechnology products

Instructor

Mike Anisfeld, President, *Globepharm Consulting, Inc.*

General Information

Three Ways To Register

1. Click www.pda.org/pdafda2011
2. Fax +1 (301) 986-1093
3. Mail PDA Global Headquarters
   Bethesda Towers,
   4350 East West Highway
   Suite 150
   Bethesda, MD 20814 USA

Venue

Renaissance Washington Hotel (Downtown)
999 9th Street, NW
Washington, D.C. 20001
Tel: +1 (202) 898-9000 **Fax:** +1 (202) 289-0947
Website: www.dcrenaissance.com

Rate: Single/Double: **$288, plus 14.5% state and local taxes.**

Rooms must be secured by August 15, 2011 in order to receive the PDA room rate. Please reference the *2011 PDA/FDA Joint Regulatory Conference & TRI Courses* to receive this special rate.

Housing at this hotel will be in high demand, so we strongly recommend making your reservations early.

Conference Registration Hours

Sunday, September 18:	1:00 p.m. – 6:00 p.m.
Monday, September 19:	7:00 a.m. – 5:30 p.m.
Tuesday, September 20:	7:00 a.m. – 5:30 p.m.
Wednesday, September 21:	7:00 a.m. – 12:00 p.m.

Course Registration Hours

Thursday, September 22:	7:30 a.m. – 4:00 p.m.
Friday, September 23:	7:30 a.m. – 4:00 p.m.

Dress/Attire

Business casual attire is recommended for the *2011 PDA/FDA Joint Regulatory Conference & TRI Courses*. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

Special Requirements

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to day@pda.org.

Group Registration

Register 4 people from the same organization and site location as a group (at the same time) for the conference and receive the 5th registration free. Other discounts cannot be applied.

Contact Information

Conference Inquiries:
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Sr. Vice President, Programs and Registration Services
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E-mail: neal@pda.org

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2011 PDA/FDA Joint Regulatory Conference & TRI Courses

September 19-23, 2011 | Renaissance Hotel | Washington, D.C.

CONFERENCE September 19-21 **EXHIBITION** September 19-21 **POST CONFERENCE WORKSHOP** September 21-22 **COURSES** September 22-23

Registration is simple and fast... Click, fax or mail: **Click:** www.pda.org/pdafda2011; **Fax:** +1 (301) 986-1093 (USA); **Mail:** PDA Global Headquarters, 4350 East West Highway, Suite 150, Bethesda, MD 20814 USA

1 Contact Information

PDA Membership Number:

Name (Last, First, MI)

Job Title

Department | Company

Mailing Address

City | State/Province | ZIP+4/Postal Code

Country | Email

Business Phone | Fax

❒ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the additional fee.)

BECOME A PDA MEMBER & SAVE

2 Conference Registration | September 19-21

Please check appropriate fee (US$).

	Member	Nonmember	Government/Health Authority Member	Government/Health Authority Nonmember*	Academic Member	Academic Nonmember*	Student Member	Student Nonmember*
Before July 9, 2011	❍ $ 1,695	❍ $ 1,944	❍ $ 700	❍ $700	❍ $ 700	❍ $ 800	❍ $ 280	❍ $ 310
July 9 - August 9, 2011	❍ $ 1,895	❍ $ 2,144	❍ $ 700	❍ $ 700	❍ $ 700	❍ $ 800	❍ $ 280	❍ $ 310
After August 9, 2011	❍ $ 2,095	❍ $ 2,344	❍ $ 700	❍ $ 700	❍ $ 700	❍ $ 800	❍ $ 280	❍ $ 310

* For this nonmember type, online registration is not available and must be faxed in.

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

Special Dietary Requirements (Please be specific):

3 Post Conference Workshop Registration | September 21-22

Please check appropriate fee (US$).

PDA Combination Products Workshop For more information visit www.pda.org/2011comboproducts	❍ **Workshop only:** $1,395	❍ **Workshop in addition to full conference purchase:** $1,345

4 Course Registration | September 22-23

Please check appropriate fee (US$).

	Price On or Before August 9, 2011				Price After August 9, 2011			
	Standard		Government/Health Authority/ Academic		Standard		Government/Health Authority/Academic	
	Member	Nonmember	Member	Nonmember*	Member	Nonmember	Member	Nonmember*
#167 Effective Investigations and Corrective Actions (CAPA) (September 22)	❍ $ 895	❍ $ 1,165	❍ $ 600	❍ $ 700	❍ $ 995	❍ $ 1,295	❍ $ 600	❍ $ 700
#376 Quality by Design for Biopharmaceuticals: Concepts and Implementation (September 22)	❍ $ 895	❍ $ 1,165	❍ $ 600	❍ $ 700	❍ $ 995	❍ $ 1,295	❍ $ 600	❍ $ 700
#175 Active Pharmaceutical Ingredients - Manufacture and Validation (September 22-23)	❍ $ 1,435	❍ $ 1,705	❍ $ 950	❍ $ 1,050	❍ $ 1,595	❍ $ 1,895	❍ $ 950	❍ $ 1,050
#267 Role of the Quality Professional in the 21st Century (September 22-23)	❍ $ 1,435	❍ $ 1,705	❍ $ 950	❍ $ 1,050	❍ $ 1,595	❍ $ 1,895	❍ $ 950	❍ $ 1,050
#307 Preparing for Regulatory Inspections for the FDA and EMA (September 22-23)	❍ $ 1,435	❍ $ 1,705	❍ $ 950	❍ $ 1,050	❍ $ 1,595	❍ $ 1,895	❍ $ 950	❍ $ 1,050
#365 Documenting and Conducting OOS Investigations (September 22-23)	❍ $ 1,435	❍ $ 1,705	❍ $ 950	❍ $ 1,050	❍ $ 1,595	❍ $ 1,895	❍ $ 950	❍ $ 1,050
#242 GMPs for Manufacturers of Sterile and/or Biotechnology Products (September 23)	❍ $ 895	❍ $ 1,165	❍ $ 600	❍ $ 700	❍ $ 995	❍ $ 1,295	❍ $ 600	❍ $ 700

5 Payment Options

All cards are charged in US$.

Group Registration: Register 4 people from the same organization and same site as a group (at the same time) for the conference and receive the 5th registration free. Other discounts cannot be applied.

❍ By Credit Card - Clearly indicate account number and expiration date and billing address. Please bill my: ❍ American Express ❍ MasterCard ❍ VISA ❍ Credit Card Guarantee Only

Total amount $

Account Number | Exp. Date

Name (exactly as it appears on card) | Signature

Billing address

City | State | Zip | Country

Wire Transfer Payments: If you require wire transfer, please contact Patresa Day at day@pda.org

PDA Federal Tax I.D. #52-1906152

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please submit payment for the prevailing rate. Please be advised that if payment or written cancellation notice is not received by **July 21, 2011**, your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on site at the prevailing rate. If you are a nonmember substituting for a member, you will be required to pay the difference for the nonmember fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. **REFUNDS: Refund requests must be in writing and faxed to +1 (301) 986-1093.** (Emails and phone messages are not accepted.) If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee at the on-site registration rate if your cancellation has not been received in writing on or before **July 21, 2011**. Refunds for Conference/Events: If your written request in received on or before **July 21, 2011**, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. Refund for Courses: If your written request is received on or before **August 23, 2011**, you will receive a full refund less the $200 processing fee. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900. **PHOTO RELEASE:** By registering for the 2011 PDA/FDA Joint Regulatory Conference & TRI Courses, I authorize PDA the right to photograph me and to use the photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership.

PDA USE ONLY Date: Check: Amount: Account:

PDA Global Headquarters
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296

"The conference was a great experience for me and I intend to be back next year."
S. Haynes

2011 PDA/FDA Joint Regulatory Conference & TRI Courses

Quality and Compliance in Today's Regulatory Enforcement Environment

September 19-23, 2011 | Renaissance Hotel | Washington, D.C.

Exhibition and Sponsorship Opportunities Are Available!

The *2011 PDA/FDA Joint Regulatory Conference & TRI Courses* is a great opportunity for your company to gain on-site exposure in front of highly qualified, bio/pharmaceutical professionals from around the world. By exhibiting or sponsoring this conference, you will connect with clients, colleagues and new prospects that are the best elements to your success. PDA offers a variety of highly effective promotional tools to meet and exceed your marketing goals.

We can help you to:
- Reinforce your brand identity andbroaden your visibility
- Target your message to a unique, qualified audience
- Gain valuable contacts

Potential clients attend the 2011 PDA/FDA Joint Regulatory Conference & TRI Courses to:
- Get updates on new trends and regulatory initiatives
- Network with experts in the bio/pharmaceutical industry
- Gather facts on innovative products and services

For more information about exhibit and sponsorship opportunities, please contact:
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